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U.S. Serial No. 10/724,793*

REMARKS

Without acquiescing to the propriety of the rejections in the Office Action dated February 9, 2005, claims 10, 18 and 27 have been amended. Entry of these amendments, reconsideration of the application, and allowance of all claims are respectfully requested in view of the remarks below. Claims 10-32 are now pending.

Specification Objection:

The Office Action objects to the terminology utilized in the application since such terminology is allegedly not present in the specification. Applicant respectfully points out that the present application incorporates U.S. Patent Application No. 10/254,036, which is now U.S. Patent No. 6,698,213 by reference. Patent '213 incorporates U.S. Patent Application No. 10/254,025, now U.S. Patent No. 6,684,646, therein. The terminology objected to and any other subject matter which is utilized in the claims would be understood to one of ordinary skill in the art from the present specification and that of patent '646. Thus, this objection is believed to be overcome.

§ 112 Rejections:

Claims 20-22, 10-32, 11, 19, and 28 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement for various reasons relating to the particular language used in these claims. Any subject matter which is recited in the claims and not disclosed in the present specification is disclosed in Patent '646, which is incorporated into patent '213, which is incorporated into the present application as noted above. Thus, this rejection is believed to be overcome.

Claims 10-32 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. In particular, claims 7-32 are rejected as being incomplete for omitting essential structural cooperative relationship of elements. Such omission is alleged to amount to a gap between necessary structural connections and such structural connections are allegedly not clearly defined in the specification. As noted above, any subject matter lacking from the present specification is

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present in the specification of Patent '646, which is incorporated into the present application by reference via Patent '213. Thus, it is respectfully submitted that any structural relationships not clear from the present specification would be clear from the specification of patent '646, which is incorporated into the present specification by reference.

§ 102 Rejections:

Claims 10, 12-18, 20-27, and 29-32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Faust et al. (U.S. Patent No. 4,090,374). In particular, Faust is alleged to disclose an apparatus having pouches/bags 17 with a handle (see FIG. 3), handle 45, support member 29, support structure 15, in temperature control unit 11 and heat transfer between a cryogenic medium and fluid in the pouches.

Amended claim 10 of the present application recites, inter alia, a support member being configured to support a container material within a temperature control unit to allow a contact area of the container material to contact a heat transfer surface separate from the support member to allow heat transfer between the heat transfer surface and biopharmaceutical material received in the container material.

Faust et al. discloses pouches storing blood components being transported and/or stored in an apparatus which includes two plates which are substantially parallel and connectable to one another. The apparatus includes a handle for transporting the apparatus. The apparatus is placed in a slot of a jig 15 which rests in a container and is submerged in liquid nitrogen. The pouch holding the blood components is held in the apparatus and submerged in the liquid nitrogen to cause freezing of the blood components. However, there is no disclosure in Faust et al. of a container having a support member configured to support a container material within a temperature control unit to allow a contact area to contact a heat transfer surface separate from the support member and to allow heat transfer between the heat transfer surface and the biopharmaceutical material. Instead, the container material is held within the apparatus in Faust et al. such that it could not contact a heat transfer surface which is separate from such an apparatus. In particular, as depicted in FIG. 4, the apparatus fits within a slot of a jig 15 such that the plates are connected to one another without the container having access to any heat transfer

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surface. Further, there is no heat transfer surface disclosed in Faust et al. which might contact such a container since the cooling is performed utilizing liquid nitrogen into which the apparatus is submerged thereby cooling the apparatus and the container. Even if the apparatus itself was considered to be a heat transfer surface it would not be a heat transfer surface separate from a support member configured to support container material within a temperature control unit. In particular, such an interpretation would require that the apparatus be considered the support member and therefore, the support member could not also be a heat transfer surface separate from such a support member. Thus, because all the features (e.g., a support member configured to support a container material within a temperature control unit to allow a contact area to contact the heat transfer surface separate from a support member to allow heat transfer between the heat transfer surface and the biopharmaceutical material) of claim 10 of the present application are not identically disclosed by Faust et al., this claim cannot be anticipated thereby. The claims dependent on claim 10 are also believed not to be anticipated for these reasons and for their own additional features.

Independent claim 18 is believed not to be anticipated for the same reasons as claim 10 and the claims depending from claim 18 are believed not to be anticipated for the same reasons and for their own additional features. Amended claim 27 and the claims depending therefrom are believed not to be anticipated for the same reasons. Thus, claims 10-32 are believed to be allowable over Faust et al.

Claims 10-32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bender (U.S. Patent No. 3,586,097). In particular, Bender is alleged to disclose an apparatus having a bag container 24, support member 21, channels 17, 18, 19, support structure 26/40, handle 28, refrigeration coil 41, temperature control unit 10, and heat transfer surface 21.

Bender discloses a plasma freezer which includes cassettes having plasma filled bags which are received in the freezer to allow freezing of the plasma. However, there is no disclosure of a support member being configured to support a container material in a temperature control unit to allow a contact area of the container material to contact a heat transfer surface separate from the support member to allow heat transfer between the heat transfer surface and biopharmaceutical material in the container material. Instead, Bender merely discloses a cassette

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having a container therein for receiving plasma. Even if the cassette was considered to be a support member, it could not be a heat transfer surface separate from such a support member. Accordingly, because all the features (e.g., a support member configured to support a container material to allow a contact area to contact a heat transfer surface separate from the support member to allow heat transfer between the heat transfer surface and the biopharmaceutical material) of claim 10 of the present application are not identically disclosed by Bender et al., this claim cannot be anticipated thereby. Independent claims 18 and 27 are believed not to be anticipated for the same reasons while the dependent claims are believed not to be anticipated for the same reasons and for their own additional features. Thus, claims 10-32 are believed to be allowable over Bender et al.

Claims 18-23, 24 and 27 stand rejected under 35 U.S.C. 102(b) as being anticipated by Moser et al. (U.S. Patent No. 5,616,301). In particular, Moser et al. discloses a thermal cycler and the Office Action alleges that referring to FIGS. 1 and 4, the system includes a container 21, ring 23, Peltier element 36, heat transfer surfaces 37, 38, recess 27 and casing 34.

Amended claim 18 of the present application recites, inter alia, a system for freezing, storing and thawing a biopharmaceutical material, which includes a container and a support member. The container has an exterior contact area and is configured to receive the biopharmaceutical material therein. The support member includes a handle and is connectable to the container. The support member is configured to be received on at least one support member within a temperature control unit and is configured to support a weight of the container to allow a heat transfer surface of a temperature control unit, separate from the support member, to contact the contact area to allow heat transfer between the heat transfer surface and the biopharmaceutical material in response to the support member being connected to the container in response to the support member being connected to the container and being received on the at least one support structure in the temperature control unit and the biopharmaceutical material being received in the container.

Moser et al. discloses an apparatus for automatic performance of temperature cycles on a number of test tubes. Each test tube is received in a holder which is constructed of a material of high thermal conductivity. However, Moser et al. does not disclose a support member having a

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handle, which is configured to be received on at least one support structure within a temperature control unit, nor such a support member being configured to support a weight of a container on the at least one support structure within the temperature control unit to allow heat transfer between the heat transfer surface and biopharmaceutical material in response to the support member being connected to the container, the support member being received on the at least one support structure of the temperature control unit and the biopharmaceutical material being received in the container as is recited in amended claim 18. Instead, Moser et al. discloses test tubes being received in a ring, but does not include a handle, nor do the test tubes receive biopharmaceutical material. Accordingly, because all the features (e.g., a support member having a handle, which is configured to be received on at least one support structure within a temperature control unit and configured to support a weight of the container on the at least one support structure to allow a heat transfer surface to contact a contact area to allow heat transfer between the heat transfer surface and biopharmaceutical materials in the container in response to the support member being connected to the container, the support member being received on the at least one support structure and the biopharmaceutical material being received in the container) of claim 18 of the present application are not identically disclosed by Moser et al., this claim cannot be anticipated thereby. Independent claim 27 is believed not to be anticipated for at least the same reasons. The dependent claims are not anticipated for the same reasons as their base independent claims and for their own additional features. Thus, claims 18, 23, 24 and 27 are believed to be allowable.

§ 103 Rejections:

The Office Action also noted that claims 10, 12-18, 20-28 and 29-32 could alternatively be obvious over Faust et al. As noted above, these claims cannot be anticipated by Faust et al. and there is no allegation in the Office Action of why these claims would be obvious over this same reference. There is no teaching, suggestion, or motivation in Faust et al. or elsewhere which would cause one to arrive at the subject matter of the pending claims, and thus these claims are believed to be allowable.

Claims 10-32 were also rejected as being in the alternatively obvious over Bender et al. in the Office Action. There is no indication in the Office Action of the reasons for this obviousness

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rejection. Further, there is no teaching, suggestion, or motivation which would cause one skilled in the art to arrive at the subject matter of the claims of the present application. Accordingly, these claims are believed not to be obvious over this reference.

Claims 11, 19, and 28 stand rejected under 35 U.S.C. § 103(a) as being over Faust et al. in view of Tumpach (European Reference No. 1,134,000) or Ammann et al. (U.S. Patent No. 6,605,213). As noted above, these claims are believed to be allowable at least for the same reasons as their base independent claims and for their own additional features. Applicant respectfully disagrees that either Tumpach or Ammann et al. would disclose the use of a support member configured to support a container within a channel of a transportation cart as recited in claims 11, 19 and 28. Instead, the Tumpach reference relates to a flexible mold for bread making which is totally unrelated to the present invention while Ammann et al. relates to an automated analyzer for performing multiple diagnostic assays simultaneously, which is also totally unrelated to the present invention. Thus, there would be no reason to combine these references with Faust et al. and such a combination would not result in the subject matter as recited in the claims of the present application.

Double Patenting:

Claim 18-32 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 6-13 and 24 of U.S. Patent No. 6,065,294. Also, claims 10-17 stand rejected for the same reason over claims 6-13 and 24 of U.S. Patent No. 6,698,213 in view of Hammerstedt et al. (U.S. Patent No. 6,065,294). The rejection over claims 18-32 is stated as being over U.S. Patent No. 6,065,294 to Hammerstedt et al., while the Office Action also references Patent "213" relative to this rejection. Applicant requests clarification as to this rejection since it is not clear which reference these claims are being rejected over.

Relative to claims 10-17, a Terminal disclaimer is included herewith over U.S. Patent No. 6,698,213, and thus this rejection is believed to be overcome.

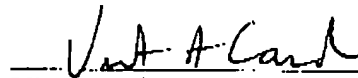
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CONCLUSION

It is believed that the application is in condition for allowance, and such action is respectfully requested.

If a telephone conference would be of assistance in advancing prosecution of the subject application, the Examiner is invited to telephone the undersigned attorney at the telephone number provided.

Respectfully submitted,



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